UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

PATSY GILLETTE Plaintiff, v. JANSSEN RESEARCH & DEVELOPMENT, LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICALS RESEARCH AND DEVELOPMENT, LLC; JOHNSON & JOHNSON COMPANY; JANSSEN ORTHO, LLC; JANSSEN PHARMACEUTICALS, INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; BAYER CORPORATION; BAYER AG; BAYER HEALTHCARE, LLC; BAYER PHARMA AG, AND BAYER HEALTHCARE PHARMACEUTICALS, INC., Defendants.	)	COMPLAINT AND JURY DEMAND Civil Action No.: _____

COMPLAINT

COMES NOW Plaintiff Patsy Gillette, by and through her undersigned counsel, and hereby submits this Complaint against Defendants Janssen Research & Development, LLC f/k/a Johnson and Johnson PHARMACEUTICALS Research and Development, LLC; Johnson & Johnson Company, Janssen Ortho,

LLC; Janssen PHARMACEUTICALS, Inc. f/k/a Ortho-McNeil-Janssen PHARMACEUTICALS, Inc.; Bayer Corporation; Bayer AG; Bayer Healthcare, LLC; Bayer Pharma AG; and Bayer Healthcare PHARMACEUTICALS, Inc., (hereinafter collectively "Defendants") for equitable relief, monetary restitution, and compensatory and punitive damages, arising from the injuries of Plaintiff Patsy Gillette as a result of her exposure to the PHARMACEUTICALS product Xarelto and hereby allege:

PARTIES

1. Plaintiff Patsy Gillette ("Mrs. Gillette") at all times relevant hereto, was and is a resident and citizen of the State of Tennessee, residing at 104 Cherokee Avenue, Church Hill, Tennessee, 37642.

2. Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC (hereinafter "Janssen R & D"), f/k/a JOHNSON AND JOHNSON PHARMACEUTICALS RESEARCH AND DEVELOPMENT LLC, is a limited liability company organized under the laws of New Jersey, with its principal place of business located at 920 U.S. Route 202, Raritan, New Jersey. Janssen R & D's sole principal or member is Centocor Research Development, Inc. (hereinafter "Centocor"), a Pennsylvania corporation with its principal place of business and nerve center located at 200 Great Valley Parkway, Malvern, Pennsylvania.

Centocor is a subsidiary or division of Johnson & Johnson, and at all times relevant herein, engaged in the research, design, marketing, sale and distribution of Xarelto.

3. Defendant JOHNSON & JOHNSON (hereinafter "J&J"), is a fictitious name adopted by Defendant JOHNSON & JOHNSON COMPANY, a New Jersey corporation which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. At all times relevant herein, Defendant JOHNSON & JOHNSON was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Xarelto.

4. Defendant Janssen R & D is the holder of the approved New Drug Application ("NDA") for Xarelto, as well as the supplemental NDA. Janssen R & D, Johnson & Johnson and Centocor all transact substantial business within the State of Georgia and throughout the United States, including the research, manufacture, sale, distribution and marketing of Xarelto, as set forth herein.

5. Defendant, JANSSEN ORTHO, LLC ("Ortho"), is a Delaware limited liability company with a principal place of business at Stateroad 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778. Ortho is a subsidiary of Johnson & Johnson. At all times relevant hereto, Defendant Ortho manufactured, and continues to manufacture, Xarelto. At all times relevant herein, Defendant Ortho derived, and continues to derive, substantial revenue from goods and products

developed, marketed, sold, distributed and disseminated and used in the State of Georgia.

6. Defendant, JANSSEN PHARMACEUTICALS, INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ("Janssen"), is a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. At all times relevant and material hereto, Janssen was, and still is, a PHARMACEUTICALS company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of PHARMACEUTICALS, including Xarelto.

7. Defendant BAYER CORPORATION ("Bayer Corp.") is, and at all relevant times was and remains, an Indiana corporation with its nerve center, headquarters and principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Bayer Corp. transacts substantial business including the research, manufacture, sale, distribution and marketing of Xarelto within the State of Georgia and throughout the United States, as set forth herein.

8. Defendant, BAYER AG ("Bayer") is a foreign company with its principal place of business in Leverkusen, Germany, which licensed Xarelto.

9. Defendant, BAYER HEALTHCARE LLC ("Bayer HC"), is a Delaware limited liability company with its principal place of business located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205 and 100 Global View Drive,

Warrendale, Pennsylvania. Bayer HC's sole member is Defendant Bayer Corporation.

10. Bayer HC is a subsidiary of Bayer and jointly developed Xarelto with J&J and Janssen R&D. Bayer HC transacts substantial business including the research, manufacture, sale, distribution and marketing of Xarelto within the State of Tennessee and throughout the United States, as set forth herein.

11. Defendant, BAYER PHARMA AG, is a pharmaceutical company domiciled in Germany.

12. Defendant BAYER PHARMA AG is formerly known as Bayer Schering Pharma AG and is the same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG is formerly known as Schering AG and is the same corporate entity as Schering AG.

13. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

14. Upon information and belief, Bayer Schering Pharma AG was renamed BAYER PHARMA AG effective July 1, 2011.

15. As part of its business, BAYER PHARMA AG is involved in the research, development, sales and marketing of pharmaceutical products including Xarelto and rivaroxaban.

16. Upon information and belief, Defendant, BAYER PHARMA AG, has transacted and conducted business in the State of Tennessee. Furthermore, Defendant BAYER PHARMA AG has derived substantial revenue from goods and products used in the State of Tennessee.

17. Upon information and belief, Defendant, BAYER PHARMA AG, expected or should have expected its acts to have consequence within the United States of America and the State of Tennessee, and derived substantial revenue from interstate commerce within the United States and the State of Tennessee, more particularly.

18. Upon information and belief, and at all relevant times, Defendant, BAYER PHARMA AG, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, to treat Deep Vein Thrombosis ("DVT") and Pulmonary Embolism ("PE"), to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

19. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC. ("Bayer Pharma"), is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Montville, New Jersey.

Bayer Pharma is the U.S.-based PHARMACEUTICALS operation of Bayer HC, a division of Bayer. Bayer Pharma is a subsidiary of Bayer and jointly developed, marketed and distributed Xarelto with J&J and Janssen R&D. At all times relevant and material herein, Bayer Pharma was, and still is, a PHARMACEUTICALS company involved in the manufacturing, distributing, sale and release for use to the general public of PHARMACEUTICALS, including Xarelto.

20. Bayer's cooperation partner, J&J and Janssen R&D, submitted the new drug application for Xarelto to the Food and Drug Administration ("FDA").

21. Defendants Janssen R&D, J&J, Ortho, Janssen, Bayer, Bayer Corp., Bayer AG, Bayer HC, Bayer Pharma AG, and Bayer Pharma shall be referred to herein individually by name or jointly as "Defendants."

22. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessor in interest, aider and abettor, co-conspirator, and joint venture of each of the remaining Defendants herein.

23. At all times mentioned herein, each of the Defendants was the agent, servant, partner, predecessor in interest, aider and abettor, co-conspirator, and joint venture of each of the remaining Defendants thereby operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

24. At all times relevant and material hereto, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, and in the State of Tennessee, either directly or indirectly, through third parties, subsidiaries and/or related entities, the anticoagulant Xarelto.

JURISDICTION AND VENUE

25. This Court has jurisdiction over this civil action pursuant to 28 U.S.C.§ 1332(a), because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiffs and the Defendants.

26. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this District.

27. This Court has personal jurisdiction over the Defendants because they have done business in the State of Tennessee, have committed a tort in whole or in part in the State of Tennessee, have substantial and continuing contact with the State of Tennessee, and derive substantial revenue from goods used and consumed within the State of Tennessee. The Defendants actively sell, market, and promote their pharmaceutical product Xarelto to physicians and consumers in this state on a regular and consistent basis.

NATURE OF THE CASE

28. Defendants, directly or by and through their agents, apparent agents, servants or employees, designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold Xarelto as an anticoagulant to be used to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation ("AFib"), to treat deep vein thrombosis ("DVT"), to treat pulmonary embolisms ("PE"), to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

29. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Xarelto.

30. When warning of safety and risks of Xarelto, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the FDA, to Plaintiffs and the public in general, that Xarelto had been tested and was found to be safe and/or effective for its indicated use.

31. Defendants applied for an initial NDA for Xarelto in July of 2008.

32. Xarelto was approved by the FDA on July 1, 2011 to reduce the risk of blood clots, DVT and PE following knee and hip replacement surgery. On November 4, 2011 Xarelto was approved as an anticoagulant primarily used to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. On November 2, 2012 the FDA expanded the use of Xarelto to the

treatment of patients with DVT and PE, as well as long-term treatment to prevent recurrence of the same.

33. According to the Defendants' marketing and informational materials, referenced in the paragraphs below, and widely disseminated to the consuming public, "Xarelto is the first and only once-a-day prescription blood thinner for patients with AFib not caused by a heart valve problem, that is proven to reduce the risk of stroke – without routine blood monitoring."[1]

34. As the Defendants state on their website, "XARELTO has been proven to lower the chance of having a stroke if you have atrial fibrillation (AFib), not caused by a heart valve problem. XARELTO is an anticoagulant, or blood-thinning medicine that works by helping to keep blood clots from forming."[2] The Defendants further claim that "it's been prescribed to more than nine million people around the world to help treat or reduce their risk of dangerous clots" and that it "begins working a few hours after you start taking it, and keeps working for as long as you take it."[3]

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[1] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM357833

[2] http://www.xarelto-us.com/how-xarelto-works

[3] *Id.*

35. Defendants further declare that for consumers with DVT and/or PE, Xarelto "reduc[es] the risk of these conditions [from] occurring again."[4]

36. Defendants claim that patients with AFib, DVT, or PE taking Xarelto do not need regular blood monitoring and that there are no known dietary restrictions. Furthermore, most patients only need to take Xarelto once a day with an evening meal and people do not have to keep track of dosage changes.[5]

37. Rivaroxaban is an oxazolidinone derivative optimized for inhibiting both free Factor Xa and Factor Xa bound in the prothrombinase complex. It is a highly selective direct Factor Xa inhibitor with oral bioavailability and rapid onset of action. Inhibition of Factor Xa interrupts the intrinsic and extrinsic pathway of the blood coagulation cascade, inhibiting both thrombin formation and development of thrombi. Rivaroxaban does not inhibit thrombin (activated Factor II).

38. Defendants routinely marketed Xarelto as a "one size fits all" drug. In their fervent marketing of Xarelto, Defendants' misinformed patients and their healthcare providers as to the necessity to routinely monitor any patient requiring a blood thinning agent. In essence, the Defendants have created a new drug, Xarelto, that is not a better alternative to warfarin (Coumadin) from a safety perspective,

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[4] https://www.xarelto-us.com/

[5] http://www.xarelto-us.com/how-xarelto-is-different

and at best, is only perhaps slightly easier to use and administer. The idea of this apparently easier-to-use anticoagulant evidently appealed to physicians, who were subject to extreme marketing and promotion by the Defendants, but ignores patient safety.

39. The Defendants' marketing materials emphasize the supposed benefits of treatment with Xarelto over warfarin, which they refer to as the Xarelto Difference – namely that Xarelto does not require patients to undergo periodic monitoring with blood tests and there are no dietary restrictions.

40. Defendants' boxed warning did not address the increased risk for serious and fatal bleeding, despite the fact that the information listed on their website originating from the Rocket AF clinical trial sponsored by Defendants, states that in comparison to warfarin, patients taking Xarelto have more gastrointestinal bleeds and need more transfusions. In spite of this reference regarding bleeds, the information is still wholly inadequate because, this information was not conveyed in the boxed warning on the Xarelto label.[6]

41. According to the Institute for Safe Medication Practices ("ISMP"), QuarterWatch Report, issued on October 3, 2012, the primary reported adverse event related to Xarelto use "was not the well-understood risk of hemorrhage. Instead, the largest identifiable category was serious blood-clot-related injury –

[6] http://www.xareltohcp.com/reducing-stroke-risk/safety.html

most frequently pulmonary embolism – the very events rivaroxaban is intended to prevent." This lack of efficacy for short term users of Xarelto post hip and knee replacement surgery resulted in about 44% of the reported adverse effects from taking Xarelto.

42. FDA clinical reviewers have stated that "rivaroxaban should not be approved unless the manufacturer conducts further studies to support the efficacy and safety of rivaroxaban" and the FDA website notes that "[a]dverse event reports of thrombocytopenia and venous thromboembolic events were identified" in relationship to Xarelto.[7] However, this information was not portrayed in the warning section on the warning label. The lack of efficacy of the medication for patients taking Xarelto to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, to treat DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery was not disclosed, resulting in patients ingesting Xarelto and physicians prescribing Xarelto without sufficient information to make an accurate decision.

43. Defendants fervently marketed Xarelto using print advertisements, online marketing on their website, and video advertisements with no regard to the

[7] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm403457.htm

accuracy and repercussions of their misleading advertising in favor of increasing sales.

44. Defendants spent significant money in promoting Xarelto, which included at least $11,000,000.00 spent during 2013 alone on advertising in journals targeting prescribers and consumers in the U.S.

45. In the January/February 2013 issue of *WebMD* magazine, Defendants placed a print advertisement that resulted in the Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) sending a letter stating that their print advertisement was "false or misleading because it minimizes the risks associated with Xarelto and makes a misleading claim." Furthermore, the advertisement states "And there are no dosage adjustments" in conflict with the product labeling approved by the FDA.[8]

46. As a result of Defendants' intense marketing, "[a]bout 130,000 U.S. prescriptions were written for Xarelto in the first three months of 2012," resulting in large profits as Xarelto costs approximately $3,000 a year versus $200 for generic warfarin.[9] In its first full year of being on the market, Xarelto garnered approximately $582 million in sales globally.

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[8] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM357833.pdf, June 6, 2013 FDA Warning Letter.

[9] Pierson, Ransdell, *Pradaxa and Xarelto: Top Heart Doctors Concerned Over New Blood Thinners*, Huffington Post,

47. Defendants' website for Xarelto claims that over 9 million people worldwide have been prescribed Xarelto. In the U.S. alone, approximately 1 million Xarelto prescriptions had been written by the end of 2013.

48. During Defendants' 2012 fiscal year, Xarelto garnered approximately $658 million in sales worldwide. Then, in 2013, sales for Xarelto increased even further to clear the $1 billion threshold commonly referred to as "blockbuster" status in the pharmaceutical industry, ultimately reaching approximately $2 billion for the fiscal year. As a result, Xarelto is now considered the leading anticoagulant on a global scale in terms of sales.

49. Due to the defective nature of Xarelto, persons who were prescribed and ingested Xarelto, including Ms. Gillette, were at increased risk for developing life-threatening bleeds. The flawed formulation of Xarelto, which according to Defendants does not require regular blood monitoring or frequent doctor follow-up, raises concerns about the risk of stroke, bleeding, and blood clots if not taken properly or absorbed properly, particularly in patients with poor renal function. In addition, "[p]rominent U.S. heart doctors [cardiologists] stress that neither new drug [Xarelto] has a known antidote for a bleeding emergency, as warfarin does."[10]

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http://www.huffingtonpost.com/2012/06/14/pradaxa-xarelto-blood-thinner-doctors-heart_n_1595971.html (last updated Aug. 14, 2012).

[10] Pierson, *supra* note 9.

50. Defendants concealed their knowledge that Xarelto can cause life threatening, irreversible bleeds from the Plaintiff, other consumers, the general public, and the medical community. The Defendants did not adequately warn of the irreversible nature of Xarelto. Specifically, Defendants did not adequately inform consumers and the prescribing medical community about the risks of uncontrollable bleeds, particularly intercranial bleeds, associated with Xarelto usage, nor did the Defendants warn or otherwise advise on how to intervene and stabilize a patient should a bleed occur.

51. Defendants concealed the dangerous side-effects of Xarelto use, despite the numerous reports filed with the FDA. In the year leading up to or about June 30, 2012, there were 1,080 Xarelto-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the FDA, including at least 65 deaths. Of the reported hemorrhage events associated with Xarelto, 8% resulted in death, which was approximately twofold the risk of a hemorrhage-related death with warfarin.

52. At the close of the 2012 fiscal year, a total of 2,081 new Xarelto-associated SAE reports were filed with the FDA in its first full year on the market, ranking tenth among other pharmaceuticals in direct reports to the FDA. Of those reported events, 151 resulted in death, as compared to only 56 deaths associated with warfarin.

53. The ISMP referred to these SAE figures as constituting a "strong signal" regarding the safety of Xarelto, defined as "evidence of sufficient weight to justify an alert to the public and the scientific community, and to warrant further investigation."

54. Of particular note, in the first quarter of 2013, the number of reported serious adverse events associated with Xarelto (680) overtook that of Pradaxa (528), another new oral anticoagulant, which had previously ranked as the number one reported drug in terms of adverse events in 2012.

55. Moreover, on a global scale, in the first eight months of 2013, German regulators received 968 Xarelto-related adverse event reports, including 72 deaths, as compared to a total of 750 reports and 58 deaths in 2012.

56. Despite the clear signal generated by the SAE data, Defendants failed to either alert the public and the scientific community, or perform further investigation into the safety of Xarelto.

57. Moreover, Defendants failed to adequately warn about the lack of an antidote to reverse uncontrolled bleeding, such as intercranial bleeding, caused by Xarelto. Defendants merely indicated that there was a risk for bleeding and side-stepped the important issue of reversing the effects of Xarelto should a bleed occur. Other safer alternatives to Xarelto, such as warfarin, have an antidote that can reverse uncontrolled bleeding.

58. Importantly, Xarelto still does not have a "black box" warning informing patients or prescribing doctors that Xarelto can cause irreversible bleeds. In fact, a label change as recent as March 2014 still fails to contain a "black box" warning regarding irreversible bleeds.

59. Aside from the warning labels, Defendants did not issue a Dear Doctor letter that sufficiently outlined the dangers of administering Xarelto to a patient. In a September 2013 letter to healthcare professionals, Defendants do not mention the lack of an antidote to Xarelto should serious and fatal bleeding occur while a patient is taking Xarelto.

60. The warning, at all material times herein, was and is simply inadequate. The Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including the Plaintiff.

61. In addition to damages for the Defendants' inadequate warnings, Xarelto also lacks any benefit sufficient to tolerate the extreme risk posed by the ingestion of the drug.

62. Xarelto is unreasonably dangerous and defective as formulated, putting consumers, including Plaintiff, at an unreasonable risk of suffering needless injuries and death.

63. Defendants willfully, wantonly and with malice withheld the knowledge of increased risk of irreversible bleeds, including intercranial bleeds, in

users of Xarelto to prevent any chance of their product's registrations being delayed or rejected by the FDA.

64. As the manufacturers and distributors of Xarelto, Defendants knew or should have known that Xarelto use was associated with irreversible bleeds, including intercranial bleeds.

65. With the knowledge of the true relationship between use of Xarelto and irreversible bleeds, rather than taking steps to pull the drug off the market, provide strong warnings or create an antidote, Defendants promoted and continue to promote Xarelto as a safe and effective treatment for AFib, DVT and/or PE prevention.

66. According to the Work Preview report, Defendants' "Xarelto . . . is estimated to be the 19th-best-selling drug in the world by 2018" and "Worldwide sales of Xarelto are expected to jump from $596 million in 2012 to $3.7 billion in 2018."[11]

67. While Defendants enjoy great financial success from their blockbuster drug, Xarelto, they continue to place American citizens at risk of severe bleeds and death.

68. Consumers, including Plaintiff Patsy Gillette, who have used Xarelto to reduce the risk of blood clots or to reduce the risk of stroke due to AFib have

[11] http://www.drugwatch.com/2013/07/23/blood-thinner-growth-more-risk/

several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with Xarelto therapy.

69. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff Patsy Gillette and her physicians the true and significant risks associated with Xarelto use.

70. As a result of Defendants' actions, Plaintiff and Plaintiff Patsy Gillette's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Mrs. Gillette would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Plaintiff Patsy Gillette's use of Xarelto were the direct and proximate result of Defendants' acts and omissions.

FACTUAL ALLEGATIONS

71. In 2013, Mrs. Gillette was diagnosed with Inferior Vena Cava (IVC) thrombus and was identified as being at high risk for blood clots. As part of her treatment, she was prescribed Xarelto to reduce the risk of blood clots.

72. In or about March 2014, Mrs. Gillette was prescribed Xarelto (20 mg), and was provided a two month prescription. When she returned to her treating physician in June, 2014, she was again given a prescription for Xarelto.

73. Mrs. Gillette took Xarelto as prescribed on a daily basis for treatment of her risk of blood clots.

74. Approximately 2 months after she began taking Xarelto, Mrs. Gillette began experiencing bleeding problems in her gums, as well as fatigue.

75. Mrs. Gillette reported these side effects to her prescribing physician.

76. On or about September 25, 2014, Mrs. Gillette began experiencing abdominal cramping accompanied with bloody bowel movements. She felt weak and because she had lost a significant amount of blood, went to Holston Valley Medical Center.

77. Upon being admitted to Holston Valley, Mrs. Gillette was diagnosed with gastrointestinal hemorrhaging. Although she was alert during most of her time at Holston Valley, Mrs. Gillette was weak and continued to feel ill.

78. While she was at Holston Valley, Mrs. Gillette's physicians noted that there was no reversal agent on the market for Xarelto, but to treat her with units of plasma and blood to help replenish the blood she had lost and reduce the effects of the Xarelto.

79. On or about September 29, 2014, Mrs. Gillette was discharged from Holston Valley.

80. As a direct result of being prescribed and properly using Defendants' Xarelto, Mrs. Gillette was caused to suffer a severe bleed requiring blood and

plasma transfusions, several CT and PET scans, a colonoscopy, and hospitalization.

81. As a direct and proximate result of the use of Defendants' Xarelto, Mrs. Gillette suffered serious and dangerous side effects including severe bleeding, as well as other personal injuries, physical pain and mental anguish, as well as diminished enjoyment of life, and expenses for hospitalization and medical treatment.

82. Plaintiff would not have used Xarelto had Defendants properly disclosed the risks associated with its use, as safer alternatives without the aforesaid risks were available.

83. The injuries and damages sustained by Plaintiff, Patsy Gillette was caused by Defendants' Xarelto.

COUNT ONE
NEGLIGENCE

84. Plaintiff incorporates by reference the factual allegations set forth above.

85. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Xarelto into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects, such as gastrointestinal bleeding.

86. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Xarelto into interstate commerce in that Defendants knew or should have known that using Xarelto created a high risk of unreasonable, dangerous side effects, including life-threatening bleeding, such as gastrointestinal bleeding, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong care, medical treatment, and monitoring and/or medications.

87. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing, producing, promoting, formulating, creating, and/or designing Xarelto without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing Xarelto without adequately testing it;

c. Not conducting sufficient testing programs to determine whether or not Xarelto was safe for use; in that Defendants herein knew or should have known that Xarelto was unsafe and unfit for use by reason of the dangers to its users;

d. Selling Xarelto without making proper and sufficient tests to determine the dangers to its users;

e. Negligently failing to adequately and correctly warn Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Xarelto;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Xarelto;

g. Failing to test Xarelto and/or failing to adequately, sufficiently and properly test Xarelto;

h. Negligently advertising and recommending the use of Xarelto without sufficient knowledge as to its dangerous propensities;

i. Negligently representing that Xarelto was safe for use for its intended purpose, when in fact, it was unsafe;

j. Negligently representing that Xarelto had equivalent safety and efficacy as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

k. Negligently designing Xarelto in a manner which was dangerous to its users;

l. Negligently manufacturing Xarelto in a manner which was dangerous to its users;

m. Negligently producing Xarelto in a manner which was dangerous to its users;

n. Negligently assembling Xarelto in a manner which was dangerous to its users;

o. Concealing information from Plaintiff in knowing that Xarelto was unsafe, dangerous, and/or non-conforming with FDA regulations;

p. Improperly concealing from and/or misrepresenting information to Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Xarelto, including but not limited to gastrointestinal bleeding and the lack of an antidote for bleeding, compared to other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

88. Defendants under-reported, underestimated and downplayed the serious dangers of Xarelto, including but not limited to irreversible bleeding.

89. Defendants negligently compared the safety risk and/or dangers of Xarelto with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

90. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Xarelto in that they:

a. Failed to use due care in designing and manufacturing Xarelto so as to avoid the aforementioned risks to individuals when Xarelto was used for treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

b. Failed to accompany their product with adequate, proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Xarelto;

c. Failed to accompany their product with adequate, proper and/or accurate warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Xarelto;

d. Failed to accompany their product with adequate, proper, and/or accurate warnings regarding the risks of all possible adverse side effects concerning Xarelto;

e. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms or severity of the side effects;

f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Xarelto; and

g. Failed to warn Plaintiff, prior to actively encouraging the sale of Xarelto, either directly or indirectly, orally or in writing, about irreversible bleeds, lack of an antidote, and/or the need for more comprehensive, and regular medical monitoring than usual to ensure early discovery of potentially serious side effects.

91. Despite the fact that Defendants knew or should have known that Xarelto caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Xarelto to consumers, like Mrs. Gillette.

92. Defendants knew or should have known that consumers such as Mrs. Gillette would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

93. Defendants' negligence was the proximate cause of Mrs. Gillette's injuries, harm, and economic and non-economic loss which she suffered and/or will continue to suffer.

94. As a result of the foregoing acts and omissions, Mrs. Gillette was caused to suffer serious and dangerous side effects including severe gastrointestinal bleeding, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continued medical treatment, monitoring and/or medications.

95. As a result of Defendants' foregoing acts and omissions Mrs. Gillette requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Mrs. Gillette is informed and believes and further alleges that she will in the future be required to obtain further personal, health, medical and/or hospital care, attention, and services.

96. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT TWO
STRICT PRODUCTS LIABILITY INCLUDING STRICT LIABILITY AS TO WARNINGS

97. Plaintiffs incorporate by reference the factual allegations set forth above.

98. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Xarelto as hereinabove described that was used by Mrs. Gillette.

99. As Defendants expected, their product, Xarelto, did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

100. At those times, Xarelto was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular to Mrs. Gillette herein.

101. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Xarelto.

102. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants' manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

103. At all times herein mentioned, Xarelto was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

104. Defendants knew or should have known that at all times herein mentioned its Xarelto was in a defective condition, and was and is inherently dangerous and unsafe.

105. At the time of Mrs. Gillette's use of Xarelto, Xarelto was being used for the purposes and in a manner normally intended, namely to reduce the risk of blood clots in patients with a history of DVT and IVC thrombus.

106. Defendants with this knowledge voluntarily designed its Xarelto in a dangerous condition for use by the public, and in particular Mrs. Gillette.

107. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

108. Defendants created a product unreasonably dangerous for its normal, intended use.

109. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Xarelto left the hands of Defendants in a defective condition and was unreasonably dangerous to their intended users.

110. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Xarelto was manufactured.

111. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to Mrs. Gillette in particular, and Defendants are therefore strictly liable for the injuries sustained by Mrs. Gillette.

112. Mrs. Gillette could not, by the exercise of reasonable care, have discovered Xarelto's defects herein mentioned and perceived its danger.

113. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including life-

threatening bleeding, such as intercranial bleeding, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risks.

114. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

115. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including life-threatening, irreversible bleeding, as well as other severe and permanent health consequences from Xarelto, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Xarelto.

116. By reason of the foregoing, the Defendants are strictly liable in tort to Mrs. Gillette for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Xarelto.

117. Defendants' defective design, manufacturing defect, and inadequate warnings of Xarelto were acts that amount to willful, and/or wanton conduct by Defendants.

118. The design, manufacturing and warnings defects in Defendants' drug Xarelto were a direct and proximate cause of Plaintiff's injuries and damages.

119. As a result of the foregoing acts and omissions, Mrs. Gillette was caused to suffer serious and dangerous side effects including severe gastrointestinal bleeding, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continued medical treatment, monitoring and/or medications.

120. As a result of Defendants' foregoing acts and omissions Mrs. Gillette requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Mrs. Gillette is informed and believes and further alleges that she will in the future be required to obtain further personal, health, medical and/or hospital care, attention, and services.

121. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT THREE
BREACH OF EXPRESS WARRANTY

122. Plaintiff incorporates by reference the factual allegations set forth above.

123. Defendants expressly warranted that Xarelto was safe and well accepted by users.

124. Xarelto does not conform to these express representations because Xarelto is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Mrs. Gillette suffered and/or will continue to suffer severe personal injuries, harm and economic loss.

125. Mrs. Gillette did rely on the express warranties of the Defendants herein.

126. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Xarelto in recommending, prescribing and/or dispensing Xarelto.

127. The Defendants herein breached the aforesaid express warranties, as their drug Xarelto was defective.

128. Defendants expressly represented to Mrs. Gillette, her physicians, healthcare providers, and/or the FDA that Xarelto was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement

surgery, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

129. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Xarelto was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

130. As a result of the foregoing acts and omissions, Mrs. Gillette was caused to suffer serious and dangerous side effects including severe gastrointestinal bleeding, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continued medical treatment, monitoring and/or medications.

131. As a result of Defendants' foregoing acts and omissions Mrs. Gillette requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Mrs. Gillette is informed and believes and further alleges that she will in the future be required to obtain further personal, health, medical and/or hospital care, attention, and services.

132. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT FOUR
BREACH OF IMPLIED WARRANTIES

133. Plaintiff incorporates by reference the factual allegations set forth above.

134. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

135. At the time Defendants marketed, sold and distributed Xarelto for use by Mrs. Gillette, Defendants knew of the use for which Xarelto was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

136. The Defendants impliedly represented and warranted to the users of Xarelto and their physicians, healthcare providers and/or the FDA that Xarelto was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

137. Defendants' representations and warranties aforementioned were false, misleading and inaccurate in that Xarelto was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

138. Mrs. Gillette, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

139. Mrs. Gillette and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Xarelto was of merchantable quality and safe and fit for its intended use.

140. Xarelto was injected into the stream of commerce by the Defendants in a defective, unsafe and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

141. The Defendants herein breached the aforesaid implied warranties, as their drug Xarelto was not fit for its intended purposes and uses.

142. As a result of the foregoing acts and omissions, Mrs. Gillette was caused to suffer serious and dangerous side effects including severe gastrointestinal bleeding, as well as other severe and personal injuries, physical

pain and mental anguish, including diminished enjoyment of life, as well as the need for continued medical treatment, monitoring and/or medications.

143. As a result of Defendants' foregoing acts and omissions Mrs. Gillette requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Mrs. Gillette is informed and believes and further alleges that she will in the future be required to obtain further personal, health, medical and/or hospital care, attention, and services.

144. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT FIVE
FRAUDULENT MISREPRESENTATION

145. Plaintiff incorporates by reference the factual allegations set forth above.

146. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to Mrs. Gillette, and/or the FDA, and the public in general, that said product Xarelto had been tested and was found to be safe and/or effective to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

147. The representations made by Defendants, were, in fact, false.

148. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

149. These representations were made by said Defendants with the intent of defrauding and deceiving Mrs. Gillette, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Xarelto, for use to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Mrs. Gillette herein.

150. At the time the aforesaid representations were made by the Defendants and, at the time Mrs. Gillette used Xarelto, Mrs. Gillette was unaware of the falsity of said representations and reasonably believed them to be true.

151. In reliance upon said representations, Mrs. Gillette was induced to and did use Xarelto, thereby sustaining severe personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

152. Defendants knew and were aware or should have been aware that Xarelto had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

153. Defendants knew or should have known that Xarelto had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

154. Defendants brought Xarelto to the market, and acted fraudulently, wantonly and maliciously to the detriment of Mrs. Gillette.

155. As a result of the foregoing acts and omissions, Mrs. Gillette was caused to suffer serious and dangerous side effects including severe gastrointestinal bleeding, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continued medical treatment, monitoring and/or medications.

156. As a result of Defendants' foregoing acts and omissions Mrs. Gillette requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Mrs. Gillette is informed and believes and further alleges that she will in the future be required to obtain further personal, health, medical and/or hospital care, attention, and services.

157. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT SIX
FRAUDULENT CONCEALMENT

158. Plaintiff incorporates by reference the factual allegations set forth above.

159. At all times during the course of dealing between Defendants and Mrs. Gillette, and/or her healthcare providers, and/or the FDA, Defendants misrepresented the safety of Xarelto for its intended use.

160. Defendants knew or were reckless in not knowing that their representations were false.

161. In representations to Mrs. Gillette, and/or her healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

a. That Xarelto was not as safe as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, treating DVT and PE, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

b. That the risks of adverse events with Xarelto were higher than those with other forms of treatment for reducing the risk of stroke and

systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

c. That the risks of adverse events with Xarelto were not adequately tested and/or known by Defendants;

d. That Defendants were aware of dangers in Xarelto, in addition to and above and beyond those associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

e. That Xarelto was defective, and that it caused dangerous side effects, including but not limited to life-threatening bleeding, such as gastrointestinal bleeding, as well as other severe and permanent health consequences, in a much more and significant rate than other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

f. That patients needed to be monitored more regularly than normal while using Xarelto;

g. That Xarelto was manufactured negligently;

h. That Xarelto was manufactured defectively;

i. That Xarelto was manufactured improperly;

j. That Xarelto was designed negligently;

k. That Xarelto was designed defectively; and

l. That Xarelto was designed improperly.

m. That Xarelto contained inadequate and/or improper warnings.

162. Defendants were under a duty to disclose to Mrs. Gillette, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Xarelto, including but not limited to the heightened risks of life-threatening bleeding.

163. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, such as gastrointestinal bleeding, and hence, cause damage to persons who used Xarelto, including Mrs. Gillette in particular.

164. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Xarelto was made purposefully, willfully, wantonly, and/or recklessly, to mislead Mrs. Gillette, and her physicians, hospitals, and healthcare

providers into reliance, continued use of Xarelto, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Xarelto and/or use the product.

165. Defendants knew that Mrs. Gillette, her physicians, hospitals, healthcare providers, and/or the FDA have no way to determine the truth behind the Defendants' concealment and omissions, and that Defendants' concealment included omissions of facts surrounding Xarelto, as set forth herein.

166. Mrs. Gillette, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on Defendants' supplied information and material, which recklessly, fraudulently and/or purposefully did not include facts that were ultimately concealed and/or omitted by Defendants.

167. As a result of the foregoing acts and omissions, Mrs. Gillette was caused to suffer serious and dangerous side effects including severe gastrointestinal bleeding, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continued medical treatment, monitoring and/or medications.

168. As a result of Defendants' foregoing acts and omissions Mrs. Gillette requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Mrs. Gillette is informed and believes and further alleges that she will in the future be required to obtain further personal, health, medical and/or hospital care, attention, and services.

169. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT SEVEN
NEGLIGENT MISREPRESENTATION

170. Plaintiff incorporates by reference the factual allegations set forth above.

171. Defendants had a duty to represent to the medical and healthcare community, and to Mrs. Gillette, the FDA and the public in general that Defendants' product, Xarelto, had been tested and found to be safe and effective to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

172. The representations made by Defendants were, in fact, false.

173. Defendants failed to exercise ordinary care in the representation of Xarelto, while involved in its manufacture, sale, testing, quality assurance, quality control, marketing and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Xarelto's high risk of unreasonable, dangerous side effects, including but not limited to irreversible bleeding.

174. Defendants breached their duty in representing Xarelto's serious side effects to the medical and healthcare community, to Mrs. Gillette, the FDA, and the public in general.

175. As a result of the foregoing acts and omissions, Mrs. Gillette was caused to suffer serious and dangerous side effects including severe gastrointestinal bleeding, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continued medical treatment, monitoring and/or medications.

176. As a result of Defendants' foregoing acts and omissions Mrs. Gillette requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Mrs. Gillette is informed and believes and further alleges that she will in the future be required to obtain further personal, health, medical and/or hospital care, attention, and services.

177. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT EIGHT
FRAUD AND DECEIT

178. Plaintiff incorporates by reference the factual allegations set forth above.

179. Defendants conducted research and used Xarelto as part of their research.

180. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, Mrs. Gillette, Mrs. Gillette's doctors, hospitals,

healthcare professionals, and/or the FDA that Xarelto was safe and effective for use as a means to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

181. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including Mrs. Gillette.

182. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and Mrs. Gillette, as well as her respective healthcare providers and/or the FDA.

183. The information distributed to the public, the FDA, and Mrs. Gillette by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

184. The information distributed to the public, the FDA, and Mrs. Gillette by Defendants intentionally included representations that Defendants' drug Xarelto was safe and effective for use to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, to reduce the risk of recurrence of

DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

185. The information distributed to the public, the FDA, and Mrs. Gillette, by Defendants intentionally included representations that Defendants' drug Xarelto carried the same risks, hazards, and/or dangers as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

186. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Xarelto was not injurious to the health and/or safety of its intended users.

187. The information distributed to the public, the FDA, and Mrs. Gillette, by Defendants intentionally included false representations that Xarelto was as potentially dangerous to the health and/or safety of its intended users as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

188. The representations were all false and misleading.

189. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Xarelto was not safe as a means of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and/or was not as safe as other means of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

190. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and Mrs. Gillette, regarding the safety of Xarelto, specifically but not limited to Xarelto being a safe means of reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

191. It was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or Mrs. Gillette, to gain the confidence of the public, healthcare professionals, the FDA, and/or Mrs. Gillette,

to falsely ensure the quality and fitness for use of Xarelto and induce the public, health care professionals and/or Mrs. Gillette to purchase, request, dispense, prescribe, recommend, and/or continue to use Xarelto.

192. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or Mrs. Gillette that Xarelto was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

193. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or Mrs. Gillette that Xarelto was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

194. The Defendants made claims and representations in their documents submitted to the FDA, to the public, to healthcare professionals, and to Mrs. Gillette that Xarelto did not present health and/or safety risks greater than other oral forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

195. These representations and others made by Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

196. These representations and others, made by Defendants, were made with the intention of deceiving and defrauding Mrs. Gillette, including her respective healthcare professionals and/or the FDA, and were made in order to induce Mrs. Gillette and/or her respective healthcare professionals to rely upon misrepresentations and caused Mrs. Gillette and/or her health care professionals to purchase, use, rely on, request, dispense, recommend, and/or prescribe Xarelto.

197. Defendants recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Xarelto to the public at large, Mrs. Gillette in particular, for the purpose of influencing the marketing of a

product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

198. Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Xarelto by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Xarelto, including but not limited to Xarelto causing irreversible bleeding.

199. The Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling Mrs. Gillette, as well as her respective healthcare professionals into a sense of security so Mrs. Gillette would rely on the representations and purchase, use and rely on Xarelto and/or that her respective healthcare providers would dispense, prescribe and/or recommend the same.

200. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including Mrs. Gillette, as well as her respective healthcare professionals would rely upon the information being disseminated.

201. Defendants utilized direct to consumer advertising to market, promote, and/or advertise Xarelto.

202. Mrs. Gillette and/or her respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and were thereby induced to purchase, use and rely on Defendants' drug Xarelto.

203. At the time the representations were made, Mrs. Gillette and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Xarelto.

204. Mrs. Gillette did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could Mrs. Gillette with reasonable diligence have discovered the true facts.

205. Had Mrs. Gillette known the true facts with respect to the dangerous and serious health and/or safety concerns of Xarelto, she would not have purchased, used and/or relied on Defendants' drug Xarelto.

206. Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on Mrs. Gillette and/or her health care professionals.

207. As a result of the foregoing acts and omissions, Mrs. Gillette was caused to suffer serious and dangerous side effects including severe gastrointestinal bleeding, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continued medical treatment, monitoring and/or medications.

208. As a result of Defendants' foregoing acts and omissions Mrs. Gillette requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Mrs. Gillette is informed and believes and further alleges that she will in the future be required to obtain further personal, health, medical and/or hospital care, attention, and services.

209. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT NINE
VIOLATION OF T.C.A. § 47-18-104 et seq.

210. Plaintiff incorporates by reference the factual allegations set forth above.

211. Defendants have a statutory duty to refrain from making false or fraudulent representations and/or from engaging in deceptive acts or practices in

the sale and promotion of Xarelto pursuant to the Tennessee Consumer Protection Act (hereinafter "the Act"), which prohibits and declares such acts or practices as unlawful.

212. Defendants engaged in unfair, deceptive, false and/or fraudulent acts and/or practices in violation of the Act through their false and misleading promotion of Xarelto designed to induce Mrs. Gillette to purchase and use Xarelto.

213. Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Publishing instructions and product material containing inaccurate and incomplete factual information;

b. Misrepresenting the nature, quality, and characteristics of the product; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

214. Defendants misrepresented the alleged benefits of Xarelto, failed to disclose material information concerning known side effects of Xarelto, misrepresented the quality of Xarelto, and otherwise engaged in fraudulent and deceptive conduct which induced Mrs. Gillette to purchase and use Xarelto.

215. Defendants uniformly communicated the purported benefits of Xarelto while failing to disclose the serious and dangerous side effects related to

the use of Xarelto, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Mrs. Gillette in the marketing and advertising campaign described herein.

216. Defendants' conduct in connection with Xarelto was impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely, and/or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Xarelto.

217. Defendants' conduct as described above was a material cause of Mrs. Gillette's decision to purchase Xarelto.

218. As a direct, foreseeable and proximate cause of Defendants' conduct in violation of the Act, Mrs. Gillette suffered damages, including personal injuries, economic damages, and non-economic damages. Defendants' conduct was further wanton, egregious and reckless so as to warrant the award of punitive damages.

219. As a result of the foregoing acts and omissions, Mrs. Gillette was caused to suffer serious and dangerous side effects including severe gastrointestinal bleeding, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continued medical treatment, monitoring and/or medications.

220. As a result of Defendants' foregoing acts and omissions Mrs. Gillette requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Mrs. Gillette is informed and believes and further alleges that she will in the future be required to obtain further personal, health, medical and/or hospital care, attention, and services.

221. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT TEN
PUNITIVE DAMAGES

222. Plaintiff incorporates by reference the factual allegations set forth above.

223. Defendants misled both the medical community and the public at large, including Mrs. Gillette and her physicians, by making false representations about and concealing pertinent information regarding Xarelto. Defendants downplayed, understated and disregarded their knowledge of the serious and permanent side effects associated with the use of Xarelto despite information demonstrating the product was unreasonably dangerous.

224. As a proximate result of Defendants' acts and omissions, Mrs. Gillette suffered internal bleeding/hemorrhaging, all resulting from her ingestion of Xarelto.

225. Defendants' actions were performed willfully, intentionally and with reckless disregard for the rights of Mrs. Gillette and the public.

226. Defendants continued to promote the safety of Xarelto, while providing to consumers no warnings or insufficient warnings about the risk of life-threatening, irreversible bleeding associated with it, even after Defendants knew of that risk.

227. Defendants' conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Mrs. Gillette, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the Court to enter judgment against the Defendants, as follows:

A. An award of general/compensatory damages in excess of the jurisdictional amount, including, but not limited to damages for past and future pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be proven at trial;

B. An award of special/economic damages in the form of past and future medical expenses, out of pocket expenses, and other economic damages in an amount to be proven at trial;

C. An award of punitive/exemplary damages pursuant to T.C.A. § 29-39-104 for the wanton, intentional, and fraudulent acts of the Defendants, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

D. Prejudgment interest;

E. Post judgment interest;

F. An award of attorneys' fees and costs, as allowed by law;

G. Leave to amend this Complaint to conform to the evidence produced at trial; and

H. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all issues triable by a jury.

DATED: July __, 2015.

Respectfully submitted,

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